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REMARKS

By this amendment, claims 1 and 18 are revised and new claim 19 is added to place this application in condition for allowance. Currently, claims 1-19 are before the Examiner for consideration on their merits.

In the outstanding Office Action, the Examiner has raised a number of issues, which are dealt with under their respective headings.

CLAIM OBJECTIONS

First, the Examiner objects to claim 18 being dependent on claim 9 since claim 18 is considered to be broader in scope than claim 9. The dependency of claim 18 is changed to claim 1 so that the conflict between claims 9 and 18 no longer exists. Therefore, the objection should be removed.

35 U.S.C. § 112, FIRST PARAGRAPH

In the Office Action, the Examiner still alleges that claim 1 does not comply with the written description requirement. In this rejection, the Examiner asserted that only scenario (2) of claim 1 was supported by the specification as originally filed.

In light of the removal of scenario (1) from claim 1, it is submitted that the rejection based on a lack of written description for claim 1 is overcome and should be withdrawn.

Applicant also submits that the separation of claims 9 and 18 also removes any question regarding written description. In the rejection, it seems that the Examiner is objecting to the fact that the dependency of original claim 12 combined this claim

with original claim 11. Original claim 11 defines different ways in which the vasodilator active compound is combined with the condom and original claim 12 defines another mode using a gel carrier. Both of these embodiments are described in the specification. Support for the original claim 11, now claim 9 is found on page 3, lines 1-4 and support for original claim 12, now claim 18, is found on page 5, lines 8-13. Therefore, there cannot be a written description problem regarding claims 9 and 18.

If there is any problem with claims 9 and 18, it may be that claim 18's dependency on claim 9 was improper since claim 18 did not further limit claim 9. However, this problem is removed by the change in claim 18's dependency. While this problem may have existed when the application was filed since claim 12 was dependent on claim 11, this error does not render the application fatally defective under 35 U.S.C. § 112, first paragraph. One of skill in the art would readily understand the meanings of original claims 11 and 12 and the change in the dependency of claim 18 merely reflects this understanding and clarification as to the limitations found in claims 9 and 18.

In the event that the Examiner would question the support for new claim 19, it is submitted that this claim does not violate the written description requirement.

As has been argued previously, scenario (1) is that scenario wherein the vasodilator active compound is applied to the surface of the condom and the compound itself is immiscible with the lubricant coated on the condom. Support for this new claim may be found in the last five lines on page 2 of the specification. This sentence reads "Preferably, the material from which the condom is formed, either

natural rubber latex or a synthetic rubber-like material, and any lubricant used therein, is immiscible with the vasodilator or the vasodilator-containing composition, whereby the vasodilator is restrained from migrating to other parts of the condom other than the zone of application.” While this sentence couches the immiscibility concept by first identifying the material of the condom and its lubricant, and then defining the immiscibility concept with later reference to the vasodilator active compound, the effect is the same; the vasodilator itself is immiscible with the lubricant. Therefore, claim 19 does not introduce subject matter not originally contained in the specification and it is in compliance with 35 U.S.C. § 112, first paragraph.

In light of the above, it is submitted that the issues raised regarding written description with respect to claims 1, 9, and 18 as well as any issue that may be raised regarding new claim 19 are dispelled.

PRIOR ART REJECTION

The Examiner now rejects the claims 1-3, 8-12, 17, and 18 based on the United States Patent No. 6,737,084 to Crosby et al. (Crosby). The Examiner also cites United States Patent No. 4,817,593 to Taller et al. (Taller) to support the contention that lubricant-containing condoms made from either latex or synthetic materials are known.

The remaining claims stand rejected based on Crosby when combined with United States Patent Nos. 5,592,945 to Moench et al. (Moench), 6,651,667 to Osterberg and 6,261,499 to Schwartz.

Applicant submits that the rejection based on Crosby, whether or not the teachings of Taller, are recognized still fails to establish a *prima facie* case of obviousness.

The issue of obviousness for claim 1 can be phrased as whether Crosby teaches or suggests a condom that has a composition containing a vasodilator active compound that is immiscible with the lubricant present on surface of the condom. Notwithstanding the rejection, Applicant contends that Crosby does not teach or suggest the feature of claim 1 and a *prima facie* case of obviousness is not established using this reference.

In making the rejection, the facts and reasoning of the rejection can be summarized as follows:

Facts

- 1) Crosby teaches a condom;
- 2) Crosby teaches applying a composition and lubricant to the condom, and the composition can include a vasodilator active compound.
- 3) The Examiner references the page 2 disclosure of the specification, which is discussed above, regarding the immiscibility of the vasodilator or vasodilator composition with a lubricant.
- 4) Taller teaches that condoms are made of latex or synthetic material and can include lubricants.

Reasoning

Applying Crosby's composition on Taller's condom "would indeed render the vasodilator immiscible with the lubricant, which is consistent with Applicant's

disclosure.”

ARGUMENT

There are a number of errors in the rejection and these errors mean that the Examiner has not established a *prima facie* case of obviousness against claim 1. The errors are set out below under their respective headings.

It is improper to use Applicant's disclosure to support the rejection of claim 1.

In the rejection, the Examiner refers to the page 2 disclosure of the specification in an apparent attempt to use this disclosure in connection with the rejection. It is completely improper to use the specification to assist in formulating the rejection and if this is the Examiner's intent, the rejection is tainted and must be withdrawn. If the Examiner is not using the disclosure of the specification to support the rejection, clarification of the rejection is requested.

Crosby does not teach the invention of claim 1.

A close reading of Crosby reveals that there is no teaching or suggestion that the composition containing the vasodilator active compound is immiscible with the lubricant used with the condom. Crosby teaches compositions for enhancement of sexual pleasure, especially for female use, which can be administered by a male condom by applying the composition to the condom prior to intercourse, for example, “in combination with other lubricants.” There is, however, no suggestion that it is necessary or desirable for the composition to be made immiscible with the lubricant.

In fact, one of skill would be led to the opposite conclusion given the use of the composition taught by Crosby. That is, Crosby teaches that the composition should

be applied in combination with other lubricants for use. Because Crosby's intent is to have the vasodilator active compound applied at the time of use, and that the lubricant would be present at this time, this would suggest to one of skill in the art that the two should be compatible, not immiscible as is the case with the present invention.

It is also important to understand the context of the invention in terms of applying the composition containing the vasodilator active compound and the need for immiscibility. The composition is applied to the condom as part of the manufacturing process rather than immediately prior to intercourse as is the case in Crosby. The purpose of the invention in this regard is to minimize the migration of the vasodilator active compound to outside the zone of application; thus the need for immiscibility. No such scenario is disclosed in Crosby or even necessary since Crosby's application of the vasodilator active compound is entirely different than the invention.

To reiterate, there is no teaching or suggestion in Crosby that would make it obvious to apply to a condom a composition containing a vasodilator active compound which is immiscible with the condom lubricant to avoid the problems of migration of the composition from its zone of application during storage. Minimizing this migration means that the composition comes into contact with the appropriate region of the vagina for absorption through the lining of the vagina to stimulate and increase the flow of blood in the labia and through the clitoris, see paragraph 4 on the first page of the specification.

In light of the above, Crosby alone cannot be said to teach the invention of claim 1.

Taller does not remedy the failings in Crosby.

In the rejection, the Examiner is apparently relying on Taller to show that latex or synthetic material condoms with lubricants are known. While the Examiner appears to use Taller in the overall rejection, the material of the condom is not specified in claim 1 so it is not understood the need for the citation of Taller to reject claim 1.

Nevertheless, the fact that lubricated condoms made of different materials are known has no bearing on the issue of obviousness. Except for the material, Crosby already teaches the combination of a lubricant and a condom. Even if Taller's teachings were employed with Crosby, this combination still does not suggest the immiscibility feature of claim 1 and a *prima facie* case of obviousness is still not made by the cited prior art.

The secondary references do not remedy the failing in Crosby.

None of Moench, Osterberg, or Schwartz teach the immiscibility limitation found in claim 1. Therefore, even if these references were combined with Crosby, the collective teachings of these references do not remedy the missing feature of Crosby. Thus, a *prima facie* case of obviousness is still not established.

New claim 19 is also not disclosed in Crosby.

New claim 19 presents a slightly different issue of obviousness as compared to claim 1. Whereas the composition containing the vasodilator active compound is immiscible with the condom lubricant in claim 1, the vasodilator active compound itself is immiscible with the condom lubricant in claim 19. Applicant submits that claim 19 is patentable for the same reasons as outlined above. That is, Crosby does

not teach the concept of a vasodilator active compound that is immiscible with the lubricant employed with the condom. Therefore, Crosby cannot be used to reject new claim 19 under 35 U.S.C. § 103(a).

If the Examiner should reject claim 19, a detailed basis for the rejection is requested. Applicant submits that the invention of claim 19 is not just any vasodilator active compound in combination with a lubricant but one that is immiscible with the lubricant to achieve the stated aim of the claim.

The same arguments as made above also apply in terms of the secondary references. Thus, claim 19 is separately patentable over the prior art of record.

Dependent claims.

Since claim 1 has been demonstrated to be patentable over the cited prior art, its dependent claims are also in condition for allowance.

Next Action

Should the Examiner make a new rejection against the claims, it is submitted that any such rejection must not be made final since the claims 1 and 19, are, in effect, the same scope as claim 1 when containing scenarios (1) and (2). Put another way, the changes to the claims cannot be used as grounds for formulating a new rejection and making it final.

SUMMARY

In light of the changes to the claims and the arguments made above, all issues raised in the outstanding Office Action have been addressed and resolved in favor of Applicant. A *prima facie* case of obviousness is not established against either of

claims 1 or 19.

Accordingly, the Examiner is requested to examine this application in light of this response and pass all claims onto issuance.

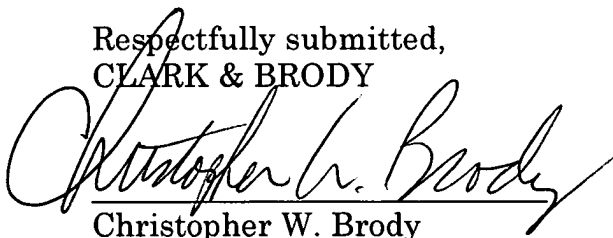
If the Examiner believes that an interview would be helpful in expediting the allowance of this application, the Examiner is requested to telephone the undersigned at 202-835-1753.

The above constitutes a complete response to all issues raised in the Office Action dated March 6, 2008.

Again, reconsideration and allowance of this application is respectfully requested.

A petition for a one month extension of time is made. Applicant no longer qualifies for small entity status, therefore a check in the amount of \$120.00 is attached for the extension of time fee. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 50-1088.

Respectfully submitted,
CLARK & BRODY

A handwritten signature in dark ink, appearing to read "Christopher W. Brody", is written over a horizontal line.

Christopher W. Brody
Registration No. 33,613

Customer No. 22902
1090 Vermont Ave. NW, Suite 250
Washington, DC 20005
Telephone: 202-835-1111
Facsimile: 202-835-1755
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